AMERICAN
ASSOCIATION
OF BLOOD BANKS

July 27, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0198: "Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components"

Dear Docket Manager:

The AABB Interorganizational Donor History Questionnaire Task Force was formed in response to a request from the Food and Drug Administration (FDA) for the development of a simplified questionnaire, with preference for a single initiative supported by the entire blood banking community. The task force is composed of representatives from the AABB, America's Blood Centers (ABC), American Red Cross (ARC), the Plasma Protein Therapeutics Association, the Centers for Disease Control and Prevention (CDC), the National Center for Health Statistics, the Department of Defense and the FDA.

The task force appreciates the opportunity to comment on the April 2004 "Guidance for Industry: Acceptable Full-length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components." The task force appreciates FDA's recognition of the materials prepared by the task force and agrees that DHQ documents will assist licensed and unlicensed manufacturers in complying with the donor suitability requirements in 21 CFR part 640. The task force understood that FDA would not be able to require blood collection facilities to implement these DHQ documents. However, we also understood that the FDA would provide incentives to use this questionnaire and would inform facilities not using this document that if they wished to continue using their questionnaire, they would be required to subject the questionnaire in use at that facility to the same kind of rigorous evaluation that was applied to the task force questionnaire. We are extremely disappointed that this was not included in the guidance as expected. This undercuts one of the expressed FDA goals of bringing some consistency in donor screening to the country.

We are also disappointed that FDA permitted deletion of questions on issues for which the FDA does not have requirements or recommendations: cancer; organ, tissue, or bone marrow transplant; bone or skin graft; and pregnancy. The task force believes that the requirements relating to these issues are essential to the safety of the blood supply. Again, this undercuts one of the expressed FDA goals of bringing some consistency in donor screening to the country.

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The task force wishes to explain that it was never our intent to require use of the flow charts that are included as part of the donor history questionnaire user brochure. These flow charts were included as an example of how to expand on and investigate the answer obtained to the required capture question. While the use of the user brochure was intended to be a requirement, the flow charts were not. In fact, the March 2002 Final Report of the Task Force specifically stated that the flow charts were provided to "offer suggested follow-up for affirmative responses to capture questions." Facilities should be free to include the flow charts in their SOPs if they so desire, but should not be required to do so. Perhaps this was not clear during the task force discussions with FDA; therefore, we request that the final guidance be more explicit in clarifying that the flow charts are not a requirement.

The task force appreciates the explanation of requirements for reporting manufacturing changes under 601.12. The ability to report such changes in an annual report should facilitate implementation of these materials in a timely manner. We further appreciate FDA's recognition that the questionnaire may be self-administered. We understand FDA's concerns that implementing a computer-assisted interactive interview procedure may present a slightly higher level of risk and would require reporting as a Changes Being Effected in 30 days supplement (CBE 30). However, as we understand it, the FDA review requirement is simply to determine that the supplement has been filed in the correct category. There is no requirement that FDA complete this review within 30 days. In fact, this means that the blood collection facility may be in jeopardy if it actually implements a computer-assisted interactive interview procedure prior to obtaining FDA approval. We request that FDA expedite review of CBE 30 submissions and notify blood collection facilities of any concerns within 30 days of the application for computer-assisted interactive interviewers.

The task force will be happy to assist the FDA in responding to comments to the draft guidance that express questions or concerns relating to the task force materials (Appendix 1 –Appendix 7) and we look forward to a continued collaborative effort.

Sincerely,

Mary J. Townsend (ltr)

Mary J. Townsend, MD
Chair
Donor History Questionnaire Task Force